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Commission sets out working definition for nanomaterials

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Report Highlights:

On October 18, the long awaited [Commission Recommendation](#) including an overarching working definition was finally adopted and published in the Official Journal of the European Union two days later. The definition is based on the size of the particles of a material, rather than hazard or risk. It is designed to be used for regulatory purposes and will cover all uses.

The definition has to bring coherence to the variety of definitions that are currently in use in different sectors and aims to provide a coherent cross-cutting reference. However, more specific definitions such as the one for food laid down in the food information Regulation will exist alongside. The definition will be reviewed in 2014 in the light of technical and scientific progress. The recommendation also delivers on a commitment made in 2009 to the European Parliament to issue a single definition that is broadly applicable to all EU legislation concerned by nanomaterials.

General Information:

Background

The Commission has been under growing pressure for a while now to produce a standard EU definition for nanotechnology and materials which could be used in all legislation. However, the involvement of several directions of the Commission in the process with conflicting interests resulted in a delay in adopting the draft recommendation: DG Enterprise is defending the interests of industry, DG Sanco and DG Environment focus on environmental and consumer health protection concerns. Another difficulty to agree on a definition was the use of a set cut-off point of a 100 nm, since there is no scientific evidence that 98 nm is hazardous while a 102 nm is not. Size needs to be just the first criterium plus a long list of other properties.

On October 18, the long awaited [Commission Recommendation](#) including an overarching working definition was finally adopted and published in the Official Journal of the European Union two days later. The recommendation should provide EU legislators with a legal coherent cross-cutting reference for nanomaterials, when adopting new or implementing existing legislation, since a variety of definitions are currently in use in different sectors as well as specific references to nanomaterials in different pieces of legislation. Special reference was made to REACH, the EU's overarching chemicals policy, since it showed during the registration that companies need more clarity about their obligations with regard to nanomaterials. The recommendation also delivers on a commitment made in 2009 to the European Parliament to issue a single definition that is broadly applicable to all EU legislation on nanomaterials.

The definition

The definition is based on a scientific opinion from the Scientific Committee on Emerging and Newly Identified Health Risks ([SCENIHR](#)) and the Joint Research Centre (JRC). A draft version of the definition was subject to a public consultation. Compared to the draft recommendation, the scope of nanomaterials is now extended to all natural and incidentally formed materials, which means that substances which are not intentionally engineered for their unique nano related properties are now also included.

A nanomaterial is defined as:

- "a natural, incidental or manufactured material" containing
- particles, in an unbound state or as an (more strongly bound) aggregate or as an (weakly bound) agglomerate and where,
- 50% or more of the particles (number size distribution) has one or more external dimensions in the size range 1 nm – 100 nm."

Some specific cases are also considered a nanomaterial:

- *Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials*
- *If there are concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.*
- *where the specific surface area by volume of the material is greater than 60 m² / cm³. However, when the 50% threshold for the number of particles applies it is a nanomaterial (definition), even if the material has a specific surface area lower than 60 m²/cm³.*

The definition is based on the size of the constituent particles of a material, rather than hazard or risk. What appears to be a scientific, technical definition has a strong political dimension since the Commission had to come up with a trade-off between conflicting interests of stakeholders and did not give priority to the precautionary principle.

Further controversy came when the Commission proposed that for a product to be counted as nano more than 50 % of the particles by number have to be nanosize compared to the 0.15 % threshold in SCENIHR's opinion. This threshold will be the focus of the review of the definition in 2014 in the light of technical and scientific progress. It is also important to note that the Commission's proposed definition is only a recommendation. The Commission published [Questions and Answers](#) which should address the concerns and comments of different stakeholders on the various aspects of the definition.

The Commission intends to use the definition as a reference for new proposals and to update existing legislation where this is foreseen by the legislator, such as the Cosmetics Regulation allowing later adaptation of the definition through the comitology procedure. The Recommendation will be used as the basis for this adaptation.

What about the specific definition in the Food Information to Consumers regulation?

The proposal on Food Information to Consumers was adopted recently, but has not yet been published. *This new regulation applies to prepackaged, processed foods states that ingredients in the form of engineered nanomaterials need to be indicated in the list of ingredients and therefore labeled.* In order to be able to label them, a definition for engineered nanomaterials was needed.

Since there is a possibility that food containing engineered nanomaterials is a novel food, the proposal also states that this definition should be considered in the context of the upcoming review of Regulation (EC) No 258/97 on novel foods and novel food ingredients. This revision of the novel foods regulation, proposed in 2008, included a definition on engineered nanomaterials but failed to pass the conciliation procedure in April 2011. Awaiting the new novel proposal, a definition for engineered nanomaterials was introduced in the food labeling proposal.

The definition in the Food labeling proposal is much more specific:

- Engineered materials
- Depending on the structure of the material a dimension over a 100nm is allowed
- It is not only focused on size but also takes into account the specific nanoscale properties

Working definition of nanomaterial	Definition in the food information to consumers
a natural, incidental or manufactured material	intentionally produced or engineered material
50% or more of the particles (number size distribution) has one or more external dimensions in the size range 1 nm – 100 nm	one or more dimensions of 100 nm or less or composed of discrete functional parts , internally or at the surface
particles, in an unbound state or as an (more strongly bound) aggregate or as an (weakly bound) agglomerate and where,	agglomerates or aggregates , may have a size above 100 nm as long as nanoscale properties are retained, such as: -those related to the large specific surface -specific physic-chemical that are different from those of the non-nanoform of the same material

Implications of the working definition

Post is following the developments regarding this new overarching working definition very closely. One of the main concerns is to understand how it will be implemented into the existing legislation

as well as how it will be incorporated into new proposals, since it covers so many diverse areas and uses. The challenges of implementing this definition refer to the determination of the proposed thresholds, how aggregates and agglomerates will be determined and how natural nanomaterials (i.e not just those manufactured) will be dealt with and the reliability of measurement methods. Considering these difficulties and uncertainties, this definition will probably be subject to a lot more controversy and criticism. As such, this working definition seems to be only a start and close monitoring of future steps will be on the agenda of the USEU nanotechnology working group.